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| 10/570,641 | 09/29/2006 | Julia Greil | G-33347-A-BCK 9942 | 2928 |
| 84983 7590 09/12/2011 SandozAG (Austria)- LUEDEKA, NEELY & GRAHAM, P.C. P.O.BOX 1871 Knoxville, TN 37901 | | | | |
| EXAMINER | | | | |
| QAZI, SABIHA NAIM | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/570,641

Applicant(s)

GREIL ET AL.

Examiner

SABIHA QAZI

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1 and 3-26 is/are pending in the application.
- 5a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1, 3-10 AND 26 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☒ Claim(s) 11-25 are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-GB/US)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date ____
- 6) ☐ Notice of Informal Patent Application
- 7) ☐ Other: ____
- 8) ☐ Paper No(s)/Mail Date 07/29/10

Non-Final Office Action

Claims 1, 3-26 are pending. Amendments are not entered.

Summary of this Office Action

1. Continued Examination under 37 CFR 1.114
2. 35 USC § 112(1) Scope of Enablement Rejection
3. Response to Remarks
4. Communication

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/10/11 has been entered.

2. Applicant's amendments changed the invention from "purification" to "treatment" as presented in RCE filed on 05/10/11.

3. **819 [R-3] Office Generally Does Not Permit Shift**

The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter.

Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). When claims are presented which the examiner holds are drawn to an invention other than the one elected,

he or she should treat the claims as outlined in MPEP § 821.03.

Where a continued prosecution application (CPA) filed under 37 CFR 1.53(d)* is a continuation of its parent application and not a divisional, an express election made in the prior (parent) application in reply to a restriction requirement carries over to the CPA unless otherwise indicated by applicant. In no other type of continuing application does an election carry over from the prior application. See *Bristol-Myers Squibb Co. v. Pharmachemie BV*, 361 F.3d 1343, 1348, 70 USPQ2d 1097, 1100 (Fed. Cir.

2004)(An original restriction requirement in an earlier filed application does not carry over to claims of a continuation application in which the examiner does not reinstate or refer to the restriction requirement in the parent application.). Where a genus claim is allowable, applicant may prosecute a reasonable number of additional species claims thereunder, in accordance with 37 CFR 1.141. Where an interference is instituted prior to an applicant's election, the subject matter of the interference issues is not elected. An applicant may, after the termination of the interference, elect any one of the inventions claimed.<

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, 3-10 and 26 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for n-BUTYLAMINE (EXAMPLES 9, 9A) and , n-DIMETHYLAMINO-1-PROPYLAMINE (EXAMPLES 6-8), does not reasonably provide enablement for any amines including the amines of claim 3.

Furthermore, there are The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims 1, 3-10.

The level of predictability in the art: There is no guidance in the specification how to make the invention as claimed. The reaction between large numbers of amines having any structure is unpredictable. Even when similar starting materials are used under the same conditions the products obtained are different.

As stated in the preface to a recent treatise:

“Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor- intensive but

otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work..... Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious)". Dorwald F. A. Side Reactions in Organic Synthesis, 2005, Wiley: VCH, Weinheim pg. IX of Preface (reference enclosed).

Thus synthesis of these compounds as claimed appears to be unpredictable.

The amount of direction provided by the inventor: The inventor provides very little direction in the instant specification for amines as claimed. See MPEP 2164.01 (b): A key issue that can arise when determining whether the specification

is enabling is whether the starting materials or apparatus necessary to make the invention are available. The Court in In re Ghiron, 442 F.2d 985,991,169 USPQ 723,727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105,210 USPQ 689, 691 (CCPA 1981). There are no starting materials provided with respect to the various substituents.

The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for practicing the claimed invention in its “full scope”. No reasonable specific guidance is provided. The specification discloses that:

Suitable primary or secondary amines in current organic solvents are soluble amines of formula I



- whereby R₁ may represent hydrogen or Y, and
- whereby X and Y may be identical or different, and X or Y may each be
 - a) hydrogen, or
 - b) an optionally substituted C₁-C₁₂-alkyl group, which is optionally interrupted by a hetero atom from the series nitrogen, oxygen or sulphur or by an alkylene group, or
 - c) an optionally substituted aryl group, or
 - d) an optionally basic aromatic heterocycle, or
 - e) an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen, or
- whereby X with R₁ may form an optionally substituted saturated or unsaturated aliphatic 3- to 8-membered ring, which may optionally contain hetero atoms from the series nitrogen or oxygen.

Claims are broad for example the heterocyclic saturated or unsaturated ring may contain 3-8 members which may contain hetero atoms. Similarly "basic heterocyclic" may contain any heterocyclic group not limited even to number of atoms.

See US Patent 5,633,279 (lines 59-67, col. 5 and lines 1-5 in col. 6) where some amines are disclosed which shows that a very large group of compounds are included as amines in present claims.

"The base additions salts may be derived from inorganic bases, and include sodium, potassium, lithium, ammonium, calcium, magnesium salts, and the like. Salts derived from organic bases include those formed from primary, secondary and tertiary amines, substituted amines including naturally-occurring substituted amines, and cyclic amines, including isopropylamine, trimethylamine, diethylamine, triethylamine, tripropylamine, ethanolamine, 2-dimethylaminoethanol, tromethamine, lysine, arginine, histidine, caffeine, procaine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, N-

alkylglucamines, theobromine, purines, piperazine, piperidine, N-ethylpiperidine, and the like. Preferred organic bases are isopropylamine, diethylamine, ethanolamine, piperidine, trimethamine, and choline”.

The instant specification does not have working examples with respect to the unlimited amines as claimed. The state of the art indicates that even when the reactants are similar, and the reaction conditions are the same, it is not necessary that it would form the same products.

The instant disclosure provides no evidence to suggest that all amines can be used when the structures are very broad in certain cases unlimited and undefined and thus does not meet the “how to use” prong of 35 USC 112, first paragraph with regard thereto.

The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed compounds could be predictably made and use as inferred by the claim and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its “full scope” a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Response to Remarks

Applicant's response filed on 05/10/11 is hereby acknowledged. Applicants arguments were found persuasive therefore rejection over Nelson US Patent 4,784,173 is withdrawn.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fetterolf Brandon can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1628